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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/731,175 | 12/05/2000 | Joseph C. Glorioso | 018484002281 | 1045 |

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EXAMINER

SHUKLA, RAM R

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1632

DATE MAILED: 06/06/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/731,175

Applicant(s)

GLORIOSO ET AL.

Examiner

Ram Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: *detailed action*.

DETAILED ACTION

1. Claims 1-44 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-28, drawn to a method of treating a connective disorder by transplanting a recombinant cell expressing a gene, classified in class 424, subclass 93.2.
 - II. Claims 29-44, drawn to a method of producing an animal model for a disease by transplanting a recombinant cell, classified in class 424, subclass 93.2.
3. Claim 1 is generic to a plurality of disclosed patentably distinct species comprising Lac Z marker gene, soluble IL-1 receptor, soluble receptor antagonist protein, a cytokine, CTL-A4, and FasL.

Claims 2 and 37 are generic to a plurality of disclosed patentably distinct species comprising synovium, cartilage, tendon, ligament, tendon, ligament, skin, bone, meniscus, intervertebral disc cells, hematopoietic progenitor cells, stromal cells, bone marrow cells, myoblasts, leukocytes, lymphoid cells and myeloid cells.

Claims 4 and 44 are generic to a plurality of disclosed patentably distinct species comprising joint space, bone marrow and blood stream.

Claim 5 is generic to a plurality of disclosed patentably distinct species comprising IL-4, IL-10, IL-13, growth factor and BMP.

Claim 10 is generic to a plurality of disclosed patentably distinct species comprising IGF, FGF and TGF.

Claim 14 is generic to a plurality of disclosed patentably distinct species comprising TIMPs, PAI and serpins.

Claims 17 and 33 are generic to a plurality of disclosed patentably distinct species comprising an adenovirus, an adeno-associated virus, a herpes virus and a retrovirus.

Claim 22 is generic to a plurality of disclosed patentably distinct species comprising sIL-1r, sTNF-alphaR, CTLA4, FasL, BMP, IGF, vIL-10, TIMP, PAIs, serpins, IL-4, IL-10 and IL-13.

Claim 27 is generic to a plurality of disclosed patentably distinct species comprising IRAP, Lac Z marker gene, soluble IL-1 receptor, soluble receptor antagonist protein, a cytokine, CTL-A4, and FasL.

Claim 31 is generic to a plurality of disclosed patentably distinct species comprising IL-alpha, IL-1 beta, IL-2, IL-8, IL-12, IL-15, IL-17, TNF-alpha, TNF-beta, gelatinase, stromelysin, collagenase, aggrecanase and iNOS.

Claim 40 is generic to a plurality of disclosed patentably distinct species comprising human IL-alpha, human IL-1 beta and TNF-alpha.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species in each of the above claims, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Inventions of the groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of treatment and a method of producing an animal disease model, which use patentably distinct material and steps and function differently. For example, the method of treatment uses an animal with a disease produced naturally whereas the method of second group produces a disease due to the expression of a particular protein. Likewise, steps of one method cannot be used for practicing the method of the other group.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If the claims are amended, added and/or canceled in response to this office action the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED.

Art Unit: 1632

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for this Group is (703) 308-4242. Any inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the Dianiece Jacobs whose telephone number is (703) 305-3388.

Ram R. Shukla, Ph.D.


RAM R. SHUKLA, PH.D
PATENT EXAMINER